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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,980	09/19/2003	Robin L. Davisson	P05473US01	8688

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DES MOINES, IA 50309-2721

EXAMINER

WILSON, MICHAEL C

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/666,980

Applicant(s)

DAVISSON, ROBIN L.

Examiner

Michael C. Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 6-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 13-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

AD

### **DETAILED ACTION**

Applicant's arguments filed 2-17-05 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The examiner of the instant application has changed. Please address all future correspondence to Examiner Michael C. Wilson, Art Unit 1632.

Claims 1-21 remain pending.

### ***Election/Restrictions***

This application contains claims 6-12 drawn to an invention nonelected without traverse on 10-21-04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 6-12 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1-5 and 13-21 remain under consideration in the instant office action.

### ***Claim Rejections - 35 USC § 112***

The rejection of claims 1-5 and 13-21 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a screening compounds of preeclampsia using mice or rats with BPH/5 phenotypes and not for screening compounds of preeclampsia using any animal with a BPH/5 phenotype has been

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withdrawn because the claims as amended are limited to screening compounds using murine animals having a BPH/5 phenotype.

Claims 1-5 and 13-21 as newly amended are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation of "murine animal" in claims 1, 13, 16, 17, 20 and 21 is new matter. Applicants point to pg 5 for support; however, support for the phrase cannot be found on pg 5. Clarification is required. Nowhere does the specification contemplate that particular "species" (murine) within that "genus" (animals) as originally claimed.

### ***Claim Rejections - 35 USC § 102***

Claims 1, 13, 16 and 17 remain rejected under 35 U.S.C. 102(b) as being anticipated by Makino (Eur. J. Pharm. 1999, Vol. 371, pg 159-167).

Makino administered adrenomedullin to rats with hypertension and preeclampsia. The rat described by Takimoto is a murine animal "with a BPH/5 phenotype" as claimed because the rat has hypertension and preeclampsia - phenotypes of BPH/5 mice.

Applicants argue the rats of Makino do not have the phenotype described in the specification. Applicants' argument is not persuasive. The claims are not limited to the "phenotype described in the specification." The claims encompass rats having any BPH/5 phenotype. The claims do not require the murine animal has every "BPH/5

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phenotype" or a phenotype not described by Makino. As such, the phrase "a BPH/5phenotype" as claimed does not distinguish the phenotype described in the specification from the phenotype described by Makino. The rats of Makino have at least two BPH/5 phenotypes, which is adequate to be considered a murine animal having "a BHP/5 phenotype" as claimed.

Claims 1-5 and 13-21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Takimoto (Science, 1996, Vol. 274, No. 5289, pg 995-998).

Takimoto administered compounds to mice with preeclampsia exhibited by hypertension, enlarged glomeruli and proteinuria and other phenotypes related to preeclampsia. The mouse with preeclampsia described by Takimoto is a "mouse with a BPH/5 phenotype" or "BPH/5 mouse" as claimed because the mouse has hypertension, enlarged glomeruli, proteinuria, etc., which indicate preeclampsia and are phenotypes of BPH/5 mice.

Applicants argue the mice of Takimoto do not have the phenotype described in the specification. Applicants' argument is not persuasive. The claims are not limited to the "phenotype described in the specification." The claims encompass mice having any BPH/5 phenotype. The claims do not require the mouse has every "BPH/5 phenotype" or a phenotype not described by Takimoto. As such, the phrase "a BPH/5phenotype" as claimed does not distinguish the phenotype described in the specification from the phenotype described by Takimoto. The mice of Takimoto have more than three BPH/5

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phenotypes, which is adequate to be considered a mouse having "a BHP/5 phenotype" or "BHP/5 mouse" as claimed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schlager "Genetic Hypertension in mice" in **HANDBOOK OF HYPERTENSION** (pg 5/10-12) is currently unnecessary to reject the claims as written but may be the closest prior art to claim 21 and may be applied to claim 21 in the future.

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Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

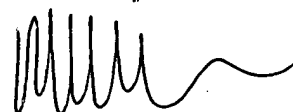
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson



**MICHAEL WILSON**  
**PRIMARY EXAMINER**